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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/997,868 | 11/28/2001 | Cornelia M. Gorman | 11669.103USW3 | 6177 |

7590 08/31/2004

Attention: Katherine M. Kowalchyk
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| EXAMINER | |
|---|---|
| GUCKER, STEPHEN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/997,868 | GORMAN ET AL. | |
| | Examiner | Art Unit | |
| | Stephen Gucker | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *12 March 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2-43* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

***Election/Restrictions***

**1.** The previous restriction requirement filed 5/24/04 is rescinded and vacated in lieu of this new restriction.

**2.** The Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-15 and 29-31, drawn to a method for treating a mammalian patient comprising obtaining a host cell having a constitutive pathway of protein secretion, and introducing nucleic acid encoding a desired polypeptide into the host cell to generate an engineered host cell, and wherein the desired polypeptide has a non-naturally occurring cleavage site, the cleavage site being recognized by an engineered host cell processing enzyme, and administering a therapeutically effective amount of said engineered host cell to said mammal, classified in class 935, subclass 62, for example.

II. Claims 16-20, drawn to a method for treating an insulin responsive disorder in a mammal comprising introducing nucleic acid encoding a variant proinsulin into a plasmid to generate a proinsulin-producing plasmid, said variant proinsulin having a non-naturally occurring cleavage site, the cleavage site being recognizable by a processing enzyme of a mammalian host cell having a constitutive protein secretion pathway, and administering a therapeutically effective amount of said proinsulin

producing plasmid to said mammal, classified in class 514, subclass 44, for example.

III. Claims 21-27, drawn to an engineered host cell, classified in class 424, subclass 93.2 or class 435, subclass 325+, for example.

IV. Claim 28, drawn to a method of preparing a host cell, classified in class 435, subclass 375, for example.

V. Claims 32-37, drawn to a different engineered host cell than in Invention III and a method of producing mature two chain relaxin polypeptide, classified in class 424, subclass 93.2 or class 435, subclass 69.1, 325+, for example.

VI. Claims 38-43, drawn to a variant of a different engineered host cell than in Invention III or Invention V, and a method of producing mature two chain relaxin polypeptide from this variant using different processing enzymes than in Invention V, classified in class 424, subclass 93.2 or class 435, subclass 69.1, 325+, for example.

**3.** Inventions III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the cell of Invention III can be used to make insulin as a pharmaceutical product, and not be

directly used as a pharmaceutical product itself, i.e. the cell does not need to be directly administered to a patient.

**4.** Inventions IV and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the cell of Invention III can be made by fusing two separate cells together to make a hybrid cell without resorting to the introduction into a single host cell of nucleic acid, as is the case with Invention IV.

**5.** Inventions IV and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the cell of Invention III can be made by fusing two separate cells together to make a hybrid cell without resorting to the introduction into a single host cell of nucleic acid, as is the case with Invention IV.

**6.** The methods of Inventions I, II, and IV involve separate and distinct process steps to accomplish separate and distinct goals, one from the other, and are therefore patentably distinct, each from the other.

**7.** The cell of Invention III is not produced or used in the methods of Invention II, and Inventions II and III are therefore patentably distinct.

**8.** The cell and processes of Invention V are not produced or used in the methods of Inventions I-IV or VI, and Invention V is therefore patentably distinct over Inventions I-IV or VI, each over the other.

**9.** The cell and processes of Invention VI are not produced or used in the methods of Inventions I-V, and Invention VI is therefore patentably distinct over Inventions I-V, each over the other.

**10.** Because these inventions are distinct for the reasons given above, and because the search and examination of these groups are different, restriction for examination purposes as indicated is proper because the search and examination of these groups is different and would pose an undue burden to the examiner.

**11.** The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply

where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

**12.** Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961. The fax phone number for this Group is currently (703) 872-9306.

SG

Stephen Gucker

August 27, 2004

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600